English language translation of Annex to International Preliminary Examination Report (PCT/IPEA/409) for PCT/EP2004/007890

## AMENDED PATENT CLAIMS DURING THE PCT-PROCEEDINGS

## PCT/EP2004/007890

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## Patent claims

- 1. An isolated regulatory CD4<sup>+</sup>CD25<sup>+</sup> T cell which comprises at least one galectin-10 as target or marker.
- 2. An isolated T-regulatory cell as claimed in claim 1 which consists of the  $CD4^{\dagger}CD25^{\dagger}\beta7^{\dagger}$  subpopulation.
- 3. An isolated T-regulatory cell as claimed in claim 1 or 2 which contains at least one human galectin-10 or a homologous protein.
- 4. An isolated T-regulatory cell as claimed in one of claims 1 to 3 which contains at least one galectin selected from the group SEQ ID No. 1 or SEQ ID No. 2.
- 5. An isolated T-regulatory cell as claimed in one of claims 1 to 4 which contains at least one galectin selected from the group SEQ ID No. 1 or SEQ ID No. 2 having the isoforms: a.) apparent molecular weight of 14 kDa and a pI of 6.7, b.) apparent molecular weight of 13.5 kDa and a pI of 5.9, c.) apparent molecular weight of 13 kDa and a pI of 5.9.
- 6. An isolated T-regulatory cell as claimed in claim 5, wherein the isoforms are selected from the group SEQ ID No. 8 to SEO ID No. 64.
- 7. An isolated regulatory T cell as claimed in one of claims 1 to 6, characterized in that at least one galectin as claimed in one of claims 1-6 is secreted, is located in the membrane or is presented on the surface of the T-

regulatory cell or in the cytosol.

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- 8. An isolated regulatory T cell as claimed in one of claims 1 to 7, characterized in that at least one galectin as claimed in one of claims 1 to 6 is concentrated in the regulatory T cell or on the surface of the regulatory T cell.
- 9. An isolated regulatory T cell as claimed in one of claims 1 to 8, characterized in that at least one nucleic acid encoding at least one galectin is present and, where appropriate, comprises one or more noncoding sequences and/or a poly(A) sequence and/or recognition sequences and/or regulatory sequences such as promoter or enhancer sequences.
- 10. An isolated T-regulatory cell as claimed in one of claims 1 to 9, characterized in that the nucleic acid sequence is selected from SEQ ID No. 6.
- 11. A marker or a target consisting of an isolated regulatory T cell which contains galectin as claimed in one of claims 1 to 10.
- 12. A binding agent which binds at least one isolated regulatory T cell as claimed in one of claims 1-10 or native regulatory T cell as claimed in claim 11 selected from the group inhibitor, agonist, antagonist, probe, antibody or immunomodulator.
- 13. A binding agent which binds at least one isolated regulatory T cell as claimed in one of claims 1-10 or native regulatory T cell as claimed in claim 11, wherein the binding agent exhibits one or more epitopes directed against galectin as claimed in one of claims 1-6 and additionally exhibits one or more epitopes directed

against a surface protein.

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- 14. A binding agent as claimed in claim 13, wherein the surface protein is selected from the group CD25, CD44, CD45, GITR, CTLA-4 and Fox P3.
- 15. A binding agent as claimed in one of claims 13 to 14, selected from the group antibody, inhibitor, agonist, antagonist, probe or immunomodulator.
- 16. A binding agent as claimed in one of claims 12 to 15, wherein the isolated regulatory T cell or native regulatory T cell containing at least one galectin as claimed in one of claims 1-6 is activated or inactivated.
- 17. A pharmaceutical which comprises at least one binding agent as claimed in one of claims 12 to 16 or isolated T-regulatory cells as claimed in one of claims 1 to 10.
- 18. A pharmaceutical as claimed in claim 17 for the treatment and therapy of diseases, specifically allergies, autoimmune diseases, in particular rheumatoid arthritis, multiple sclerosis or Crohn's disease, chronic inflammation, asthma, immunodeficiency diseases, AIDS, transplant rejection and cancer diseases as well as diabetes.
- 19. A pharmaceutical as claimed in claim 18, wherein the autoimmune diseases are selected from the group: alopecia areata, Bechterew's disease, antiphospholipid syndrome, Addison's disease, Behcet's disease, sprue celiac disease, chronic fatigue immune dysfunction syndrome (CFIDS), polyneuropathy, Churg-Strauss syndrome (granulomatosis), CREST syndrome (Raynaud's syndrome), cold agglutinin disease, cryoglobulinemia, fibromyalgia, fibromyositis, Basedow's disease, Guillain-Barré

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syndrome, idiopathic pulmonary fibrosis, idiopathic thrombocytopenia, IgA nephropathy, lichen planus, Ménière's disease, polyarteritis nodosa, polychondritis, polyglandular syndrome, polymyalgia rheumatica, primary agammaglobulinemia, biliary cirrhosis, psoriasis, Reiter's disease, sarcoidosis, Sjögren's disease, Takayasu arteritis, vasculitis, vitiligo and Wegener's granulomatosis.

- 20. A test system which comprises at least one binding agent and at least one regulatory T cell containing galectins as claimed in one of claims 1-6 for identifying suitable binding agents or regulatory T cells, preferably those possessing elevated suppressive properties.
- 21. A test system which comprises at least one regulatory T cell containing galectins as claimed in one of claims 1-6 and at least one target cell, in particular T cell, B cell, macrophage, predendritic cell, dendritic cell, embryonic cell and/or fibroblast which is/are incubated with at least one regulatory T cell for the in-vitro detection of suppressive properties, in particular suppression of the cellular immune response of effector cells of the immune system, in particular B cells, NK cells, preferably T cells and T helper cells.
- 22. The test system as claimed in claim 21, wherein the effector cells are mammalian cells, in particular human or murine cells or an immune cell line and/or a cultured primary immune cell.
- 23. The test system as claimed in claim 21 or 22, wherein at least one further substance which can elicit an immune response, such as proteins, epitopes, protein fragments, antigens or binding agents, is/are incubated.

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- 24. A diagnostic agent which comprises a test system as claimed in one of claims 20 to 23 and, where appropriate, a pharmaceutically acceptable support.
- 25. A diagnostic agent as claimed in claim 24 for diagnosing diseases, specifically allergies, autoimmune diseases, in particular rheumatoid arthritis, multiple sclerosis or Crohn's disease, chronic inflammation, asthma, immunodeficiency diseases, AIDS, transplant rejection and cancer diseases as well as diabetes.
- 26. A diagnostic agent as claimed in claim 25 for diagnosing diseases, specifically autoimmune diseases selected from the group: alopecia areata, Bechterew's disease, antiphospholipid syndrome, Addison's disease, Behcet's disease, sprue celiac disease, chronic fatigue immune dysfunction syndrome (CFIDS), polyneuropathy, Churg-Strauss syndrome (granulomatosis), CREST syndrome (Raynaud's syndrome), cold agglutinin disease, cryoglobulinemia, fibromyalgia, fibromyositis, Basedow's disease, Guillain-Barré syndrome, idiopathic pulmonary fibrosis, idiopathic thrombocytopenia, IgA nephropathy, lichen planus, Ménière's disease, polyarteritis nodosa, polychondritis, polyglandular syndrome, polymyalgia rheumatica, primary agammaglobulinemia, biliary cirrhosis, psoriasis, Reiter's disease, sarcoidosis, Sjögren's disease, Takayasu arteritis, vasculitis, vitiligo and Wegener's granulomatosis.